

REMARKS

This application has been carefully reviewed in light of the Office Action dated March 1, 2004. Claims 1-37 remain in this application. Claims 1, 2, 3, 6, 7 and 8 are the independent Claims. It is believed that no new matter is involved in the amendments or arguments presented herein. Reconsideration and entrance of the amendment in the application are respectfully requested.

Claim Objection

Claims 11-13, 15, 17-20, 22-26, and 29-37 were objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. Applicant respectfully traverses this rejection. Applicant respectfully points out that Claims 11-13, 15, 17-20, 22-26, and 29-37 are **Dependent** claims and **not Multiple Dependent** Claims. MPEP § 608.01(n) (I) defines a multiple dependent claim as “

a dependent claim which refers back in the
alternative to more than one preceding independent
or dependent claim

Here, the objected to claims 11-13, 15, 17-20, 22-26, and 29-37, do not refer to more than one preceding claim, but only to one claim. As such, those claims are dependent and not multiple dependent claims. Moreover, although a multiple dependent claim may not depend on another multiple dependent claims, there is no prohibition against a dependent claim depending from a multiple dependent claim.

§ 608.01(n)(F) of the MPEP, titled “Handling of Multiple Dependent Claims by the Examiner,” provides a Table which makes clear that a claim (such as claim 7 in the Table) can depend from a multiple dependent claim (claim 6 in the Table).

Reconsideration and withdrawal of the above objection are respectfully requested.

Art-Based Rejections

Claims 1-10, 14, 16, 21, and 27-28 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,533,968 (Muni) and U.S. Patent No. 5,853,408 (Muni II). Applicant respectfully traverses the rejections and respectfully submits that the claims herein are patentable over the applied art of record in light of the arguments below.

The Muni Reference

The applied Muni reference discloses a catheter with a distal section which includes an outer tubular member secured to an inner tubular member over a length. (*See, Muni, abstract; Col. 2, lines 50-52*). According to Muni, the disclosed catheter includes a catheter shaft having an outer tubular member with an expandable distal section which expands elastically upon the introduction of fluid under a pressure within a first pressure range to a larger diameter and which contracts by elastic recoil upon the withdrawal of the inflation fluid. (*See, Muni, abstract; Col. 2, lines 50-52*).

The Muni II Reference

The applied Muni II reference is concerned with altering the mechanical properties of various angioplastic surgical devices in order to enhance their transportability through the vascular system by changing their operating temperature while situated within the body. (*See, Muni II, abstract; Col. 2 line 31 to Col. 2, lines 35-39*). According to Muni II, the temperature increases are utilized to increase flexibility or cause devices to assume certain configurations while a temperature decrease serves to increase stiffness and rupture strength. (*See, Muni II, Col. 2, line 31 to Col. 3, line 51*).

The Claims are Patentable Over the Cited References

The present application is generally directed to a balloon catheter used in medical treatment.

As defined by independent Claim 1, a balloon catheter includes a balloon and a plurality of tubular members. The balloon catheter has a structure in which a first tubular member having as one purpose thereof to allow a slidable guide wire to pass through, the interior thereof is deployed passing through the interior of the balloon. The balloon and the outer surface of the first tubular member are fused concentrically in the vicinity of the distal end of the catheter. A Shore hardness of a material configuring the outermost surface of at least that portion of the first tubular member where the balloon is fused is lower than the Shore hardness of a material configuring the balloon.

As defined by independent Claim 2, a balloon catheter includes a balloon and a plurality of tubular members. The balloon catheter has a structure in which a first tubular member having as one purpose thereof to allow a slidable guide wire to pass through, the interior thereof is deployed passing through the interior of the balloon. The balloon and the outer surface of the first tubular member are fused concentrically in the vicinity of the distal end of the catheter. Flexural modulus of a material configuring the outermost surface of at least that portion of the first tubular member where the balloon is fused is lower than the flexural modulus of a material configuring the balloon.

As defined by independent Claim 3, a balloon catheter includes a balloon and a plurality of tubular members. The balloon catheter has a structure in which a first tubular member having as one purpose thereof to allow a slidable guide wire to pass through, the interior thereof is deployed passing through the interior of the balloon. The balloon and the outer surface of the first tubular member are fused concentrically in the vicinity of the distal end of the catheter. The melting point of a

material configuring the outermost surface of at least that portion of the first tubular member where the balloon is fused is lower than the melting point of a material configuring the balloon

The applied references fail to disclose or suggest the above features of the claims of the present invention. In particular, the applied references fail to disclose or suggest "wherein a Shore hardness of a material configuring the outermost surface of at least that portion of said first tubular member where said balloon is fused is lower than the Shore hardness of a material configuring said balloon," as required by independent Claim 1.

Moreover, the applied art of the record does not teach or suggest "wherein flexural modulus of a material configuring the outermost surface of at least that portion of said first tubular member where said balloon is fused is lower than the flexural modulus of a material configuring said balloon, as required by independent Claim 2.

Furthermore, the applied art of the record is not seen to disclose or suggest "wherein melting point of a material configuring the outermost surface of at least that portion of said first tubular member where said balloon is fused is lower than the melting point of a material configuring said balloon," as required by independent Claim 3.

On pages 3 and 4 of the Office Action, it is stated that the rejected claims are anticipated under § 102(b) because "collectively, Muni et al lists a number of materials and references incorporated by reference wherein the shore hardness, flexural modulus, and therefore the melting point is greater for the balloon than the tubular member...." Applicant respectfully traverses this rejection.

The applied Muni reference discloses a catheter with a distal section which includes an outer tubular member secured to an inner tubular member over a length. (*See, Muni, abstract; Col. 2, lines 50-52*). According to Muni, the disclosed

catheter includes a catheter shaft having an outer tubular member with an expandable distal section which **expands elastically upon the introduction of fluid under a pressure within a first pressure range to a larger diameter and which contracts by elastic recoil upon the withdrawal of the inflation fluid.** (*See, Muni, abstract; Col. 2, lines 50-52*). Similarly, Muni II concerns altering the mechanical properties of various angioplastic surgical devices in order to enhance their transportability through the vascular system by changing their operating temperature while situated within the body. (*See, Muni II, abstract; Col. 2 line 31 to Col. 2, lines 35-39*). According to Muni II, the **temperature increases are utilized to increase flexibility** or cause devices to assume certain configurations while a temperature decrease serves to increase stiffness and rupture strength. (*See, Muni II, Col. 2, line 31 to Col. 3, line 51*).

However, neither Muni I nor Muni II disclose or even suggest “wherein a Shore hardness of a material configuring the outermost surface of at least that portion of said first tubular member where said balloon is fused is lower than the Shore hardness of a material configuring said balloon,” as required by independent Claim 1. Similarly, neither of these references teach or suggest “wherein flexural modulus of a material configuring the outermost surface of at least that portion of said first tubular member where said balloon is fused is lower than the flexural modulus of a material configuring said balloon, as required by independent Claim 2. Furthermore, neither Muni I nor Muni II is seen to disclose or suggest “wherein melting point of a material configuring the outermost surface of at least that portion of said first tubular member where said balloon is fused is lower than the melting point of a material configuring said balloon,” as required by independent Claim 3.

The Office Action contention that “several of the material are present and disclosed for use in the manufacture of balloon catheters of Muni...” (*See, Office*

Action, pages 3-4). Applicant respectfully submits that this standard fails to comply with the requirements of the MPEP. For example, according to the MPEP §2144.04, "the mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. ***The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device.***" Ex parte Chicago Rawhide Mfg. Co., 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

Should the Examiner persist in maintaining this ground of rejection, Applicant respectfully requests that the Examiner provide an affidavit identifying the disclosed material and the motivation for the suggested combination.

Since the cited reference fails to disclose, teach or suggest the above features recited in independent Claims 1, 2 and 3, these references cannot be said to anticipate nor render obvious the invention which is the subject matter of those claims.

Accordingly, independent Claims 1, 2 and 3 are believed to be in condition for allowance and such allowance is respectfully requested.

Applicant respectfully submits that independent Claims 6, 7 and 8 are allowable for at least the same reasons as those discussed in connection with independent Claims 1, 2 and 3.

The remaining claims depend either directly or indirectly from independent Claims 1, 2, 3, 6, 7 and 8 and recite additional features of the invention which are neither disclosed nor fairly suggested by the applied references and are therefore also believed to be in condition for allowance.

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Conclusion

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California telephone number (213) 337-6809 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,
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